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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,058	04/02/2004	John E. Baker	BA-32448(1)	2664
22202	7590	11/03/2004	EXAMINER	
WHYTE HIRSCHBOECK DUDEK S C 555 EAST WELLS STREET SUITE 1900 MILWAUKEE, WI 53202			MAYER, SUZANNE MARIE	
		ART UNIT	PAPER NUMBER	1653

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/817,058	BAKER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Suzanne M. Mayer, Ph.D.	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-46 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-46 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 02 April 2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____.   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>07-07-2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

**DETAILED ACTION**

1. Claims 1-46 are pending in this application and have been considered by the Examiner.

***Priority***

2. The claim of benefit of provisional application US 60/460,684 (04-04-2004) is acknowledged.

***Information Disclosure Statement***

3. The information disclosure statement (IDS) submitted on 07-07-2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation of administering erythropoietin (EPO) to a patient renders this claim indefinite because administering EPO to any patient who is

not suffering the effects of myocardial ischemia is subsequently not going to reduce the effects of this condition if this patient is not suffering from it.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2, 4, 6-16, 18, 24, 29-30, 32-33, 38-40 and 43-46 are rejected under 35 U.S.C. 102(a) as being anticipated by Calvillo et al. Calvillo et al. teach a method of treating myocardial ischemia-reperfusion injury through the administration of 5000 U/kg of recombinant human erythropoietin to rats. Administration is performed intraperitoneally and administered as pretreatment, or prior to ischemia, or at reperfusion itself (see p. 4803, 2<sup>nd</sup> column, 1<sup>st</sup> full paragraph).

8. Claims 1-8, 10-18, 24-31 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Stamler.

Stamler teaches methods of reducing myocardial ischemia in patients by administration of erythropoietin (EPO) at a concentration 1-10,000 U/kg (see p. 2,

paragraph [0009]). It is assumed that the EPO blood concentration during treatment will preferentially want to hold the level at 1-100 mU/ml and thus the amount of EPO administered to hold it at this level is determined by the patient's sex, weight, symptoms and the species of animal (see p. 10, paragraph [0112]) (normal levels are between 5-50 mU/ml). The method of administration can be parenteral (e.g., subcutaneous or intramuscular), oral, topical, nasal, or slow release microcarriers (see p. 4, paragraph [0051]). Therefore the limitation of the instant claims reciting that administration of EPO is for 'about 1-35 minutes' has been anticipated according to these administration methods because 'about' has a broad open interpretation and all of these methods of administration will deliver EPO in about one minute with the slow release microcarriers delivery occurring in a length of time much longer than about one minute. Thus, the limitations of claims 1-8, 24 and 29-31 have been met.

On p. 2, paragraph [0012] Stamler teaches that administration of EPO for ischemia-reperfusion can be done prior to, at the onset of, or following cardiac injury which would encompass prior to the onset of ischemia, or at or following reperfusion. The ischemia-reperfusion can be caused by myocardial infarction, trauma, cardiac arrest, heart surgery, heart transplantation or surgical repair, to name just a few (see claim 49, p. 12). Furthermore, the prevention of an ischemic event can be performed to prevent organ damage during an organ or tissue transplantation by administering EPO to the organ donor prior to or at the time of the organ removal. Thus claims 10-18 have been anticipated.

Claims 19-23 are drawn to methods of reducing myocardial ischemia in an organ transplant recipient comprising the step of exposing the organ to be transplanted to a pharmaceutically acceptable formulation. Stamler teaches on p. 2, paragraph [0015] a method to prevent organ damage during organ transplantation by administering to the *donor* a protective effective amount of EPO so that the organ will be protected during transplantation. Furthermore, any organ or tissue that is capable of being transferred is taught. Thus, Stamler teaches the method encompassed by these claims because effectively administering EPO to the donor will ultimately elicit a cardio protective effect of the organ that will be transplanted.

Claim 25 claims the method of administration of an effective amount of EPO to prevent or reduce injury due to myocardial ischemia so that protein kinase is activated which will help reduce the ischemic injury. Stamler teaches on p.2, paragraph [0011] that modulation of a cardioprotective signaling pathway can be achieved through the administration of EPO which will enhance or maintain these pathways. One of these pathways which is disclosed is the mitogen activated protein kinase (MAPK) and nitric oxide synthase. Thus the limitations of claim 25 and 26 have been met.

9. Claims 32-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Cynshi et al. Cynshi et al. disclose in Examples 1-6 (columns 6-8) of U.S. Patent 4,732,889, pharmaceutically acceptable liquid and freeze-dried compositions of erythropoietin. Since the instant claims of this rejection claim a pharmaceutical composition of erythropoietin, it is an inherent property of the composition itself for whichever way this composition is used or how it is formulated. In other words, an intended use or

formulation of a composition does not further limit the claim and composition. It is the composition itself which is being claimed and not the method of formulating or using. Therefore the composition which sets forth the limitations of each of these claims has been met and these claims are rejected.

10. Claims 32-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Stamler. Stamler discloses pharmaceutically acceptable compositions/carriers of erythropoietin (see p.5, paragraph [0054]) which can be administered in a variety of ways including the following: parenterally, infusion, intranasal, transdermal, suppository, intraperitoneal, subcutaneous and intramuscular (see p. 4, paragraph [0051]).

#### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stamler in view of Brines et al.

Stamler teaches on p. 2, paragraph [0015] a method to prevent organ damage, of for example a heart, during organ transplantation by administering to the *donor* a protective effective amount of EPO so that the heart will be protected during transplantation. Thus, Stamler teaches effective administration of EPO to a donor that

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will ultimately elicit a cardio protective effect to the heart to be transplanted. Stamler, however, does not teach the exact range.

Brines et al. teach a method of administering EPO to effectively protect erythropoietin-responsive cells, tissues and organs and that this effect can induce protection of the myocardium from ischemic injury (see Example 3, p. 10). Furthermore, they teach that this method can be effective in treating organs to be transplanted whereby the organ or tissue that is transplanted in perfused with an effective amount of an EPO solution, the amount of EPO being 1-25 U/ml and treatment can occur past the recommended 30 hour time limit (see p. 9, paragraph [0069]).

One would be motivated to treat organs to be transplanted by perfusing EPO into them in an effective amount of 1-25 U/ml because Brines et al. teach to do so. Furthermore, one would be further motivated to do so in a heart organ because the method of Stamler and Brines et al. teaches that treating a patient with EPO prevents or treats the myocardium/heart from ischemia, thus the heart must obviously possess erythropoietin responsive cells. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to treat or infuse a heart or other organ to be transplanted with EPO in an effective amount as outlined by Brines et al. in order to prevent the onset of myocardial ischemia in a transplant recipient and to treat the organ to be transplanted for an extended period of up to 30 hours, which most certainly encompasses the 5-30 minute time frame to which the instant claims are limited.

***Conclusion***

13. No claims are allowed.
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Mayer, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday from 8.30am to 5.00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*SMM*  
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21 October, 2004

*Robert A. Wax*  
ROBERT A. WAX  
PRIMARY EXAMINER  
*Art Unit 1653*